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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E-1115]

Determination of Regulatory Review Period for Purposes of Patent Extension; Lumbar I/F Cage®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Lumbar I/F Cage® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Claudia V. Grillo,
Regulatory Policy Staff (HFD-007),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-5645.

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SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Lumbar I/F Cage®. Lumbar I/F Cage® is indicated for an open posterior approach using autogenous bone graft in patients with

degenerative disc disease at one or two spinal levels from L2-S1 whose condition requires the use of interbody fusion combined with posterolateral fusion and posterior pedicle screw fixation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lumbar I/F Cage® (U.S. Patent No. 4,834,757) from DePuy AcroMed, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 10, 1999, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Lumbar I/F Cage® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Lumbar I/F Cage® is 2,631 days. Of this time, 1,708 days occurred during the testing phase of the regulatory review period, while 923 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: November 22, 1991. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective November 22, 1991.

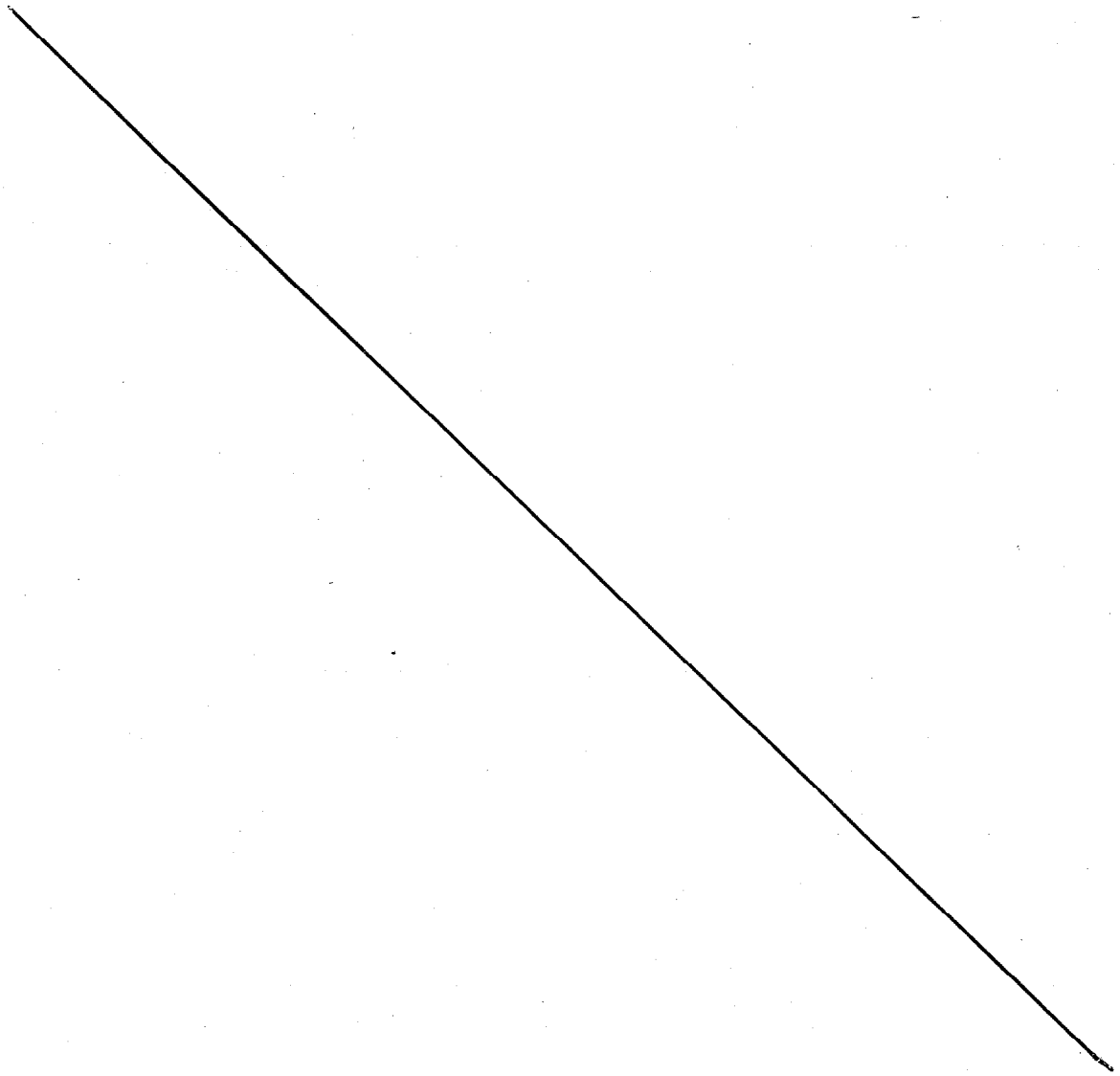
2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): July 25, 1996. FDA has verified the applicant's claim that the premarket approval application (PMA) for Lumbar I/F Cage® (PMA P960025) was initially submitted July 25, 1996.

3. The date the application was approved: February 2, 1999. FDA has verified the applicant's claim that PMA P960025 was approved on February 2, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,776 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before [insert date 60 days after date of publication in the FEDERAL REGISTER], submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before [insert date 180 days after date of publication in the FEDERAL REGISTER], for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the



docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23 1999.
December 23, 1999

Jane A. Axelrad

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Associate Director for Policy
Center for Drug Evaluation and Research